UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

PROFESSIONAL DRUG COMPANY, INC., on behalf of itself and all others similarly situated,

Plaintiff,

v.

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, RANBAXY PHARMACEUTICALS, INC., RANBAXY INC., RANBAXY LABORATORIES, LTD., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA USA, INC., DR. REDDY'S LABORATORIES LTD., and DR. REDDY'S LABORATORIES, INC.,

Defendants.

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated,

Plaintiff,

V.

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, RANBAXY PHARMACEUTICALS, INC., RANBAXY INC., RANBAXY LABORATORIES, LTD., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA USA, INC., DR. REDDY'S LABORATORIES LTD., and DR. REDDY'S LABORATORIES, INC.,

Defendants.

CIVIL ACTION NO. 12-cv-11609-WGY

CIVIL ACTION NO. 12-cv-11711-WGY

[PROPOSED] PROTECTIVE ORDER

Based upon the representations and submissions of the parties, the Court's records and files in this matter, and good cause appearing therefore, the Court enters the following Protective Order (hereinafter "Order" or "Protective Order") to govern the discovery, use and handling of Protected Material, as defined in Paragraph 1, produced by parties and non-parties in the above-captioned cases. IT IS HEREBY ORDERED that:

- 1. <u>Definition of Protected Material.</u> As used herein, "protected material" refers to information or documents produced during the course of this litigation that (1) a party in good faith reasonably believes might be injurious to that party's business interests and (2) that includes a trade secret or confidential research, development, business, or commercial information that would not normally be revealed to another as set forth in Fed. R. Civ. P. 26(c)(1)(G), or (3) other information required by law to be kept confidential, e.g., HIPAA-protected information.
 - 2. <u>Disclosure and Use of Protected Material.</u>
- a. Protected Material disclosed by a plaintiff, a defendant, or a third party (hereinafter "Producing Party") to any other party (hereinafter "Receiving Party") pursuant to discovery in this action, along with any copies, excerpts, or summaries thereof and materials containing information derived therefrom, as well as any knowledge or information derived from any of the aforementioned items, shall be used solely for purposes of this action and not for any other purpose, including, without limitation, any business or commercial purpose.
- b. If a Receiving Party is served with a subpoena or a discovery request in an action other than the above-captioned case or any other request seeking by legal process the production of Protected Material, such Receiving Party shall promptly notify the Producing Party, and inform the persons seeking discovery in writing (with copy to the Producing Party and

the Court) that providing the Protected Material would be a violation of this Protective Order. In no event shall the person receiving the subpoena or other process produce Protected Material of any Producing Party in response to the subpoena or other process unless and until such person has: (i) received written authorization from counsel for the Producing Party to produce said Protected Material or (ii) been ordered to do so by a court of competent jurisdiction.

- c. The recipient of any Protected Material that is provided under this Order shall maintain such information in a secure and safe area and shall exercise at least the same standard of due and proper care with respect to the storage, protection, custody, use, and/or dissemination of such information as is exercised by the recipient with respect to its own proprietary information.
 - 3. Confidentiality Legend Designations.
- a. Any Producing Party producing documents, things, information or other materials in the above-captioned case ("Produced Material") for inspection or review by a Receiving Party shall designate any Protected Material as "Confidential" or "Attorney Confidential."
- b. The Attorney Confidential designation shall be limited to Protected Material which a party in good faith reasonably believes contains or comprises sensitive, non-public financial, marketing, customer, clinical, regulatory, research, development, scientific or commercial information, or any other information that a party believes in good faith could be used by a competitor to harm its business. The Attorney Confidential designation may alternatively be referred to as Highly Confidential.
- c. The Confidential designation shall be used for all Protected Material not designated as Attorney Confidential.

- 4. <u>Labeling of Protected Material.</u>
- a. The designation of Protected Material for purposes of this Order shall be made in the following manner:
 - (1) Each page of each document produced pursuant to discovery in this action shall bear, by Producing Party, a unique identifying number (hereinafter or "identifying number" or "Bates Number"). If a third party produces documents without labeling them with unique identifying numbers, the party that requested the third party's documents shall label the third-party documents and distribute them to all parties to this litigation.
 - (2) With regard to written material (including transcripts of depositions or other testimony) and electronic images (such as TIFFs or PDFs) that is Protected Material, each page should be marked consistent with the designation described in Paragraph 3 that is appropriate for that document, and
 - (3) With regard to non-written material, such as recordings, magnetic media, photographs and things, the designation consistent with Paragraph 3 should be affixed to the material in any suitable manner.
- b. Designation of transcripts of any deposition disclosing Protected Material shall be made in accordance with Paragraph 15.
- c. Failure to affix the designations set forth in this Paragraph 4 shall not amount to a waiver of any confidential status. Rather, in the event a party discovers a failure to properly designate Protected Material in accordance with this paragraph, such failure shall be remedied in accordance with Paragraph 21.

5. Treatment of Protected Material from the Underlying Patent Litigations.

Plaintiffs' proposal

a. Information disclosed or produced by any party or nonparty in earlier patent infringement litigation involving patents ostensibly covering the drug Nexium that were designated as confidential shall be treated as protected material under this Order. This Court shall maintain jurisdiction over and adjudicate any challenge to production of documents in these actions by any party or non-party, and shall address in the first instance any challenge based on the assertion that the production of such documents is governed by an order entered in such earlier patent infringement litigation.

[Plaintiffs seek to have this Protective Order cover all patent actions involving Nexium, not just those identified in the complaint].

Defendants' proposal

Information disclosed by any party or nonparty in AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al., No. 08-cv-00328 (D.N.J.) (Pisano, J.); AstraZeneca AB, et al. v. Ranbaxy Pharmaceuticals, Inc., et al., No. 05-cv-05553 (D.N.J.) (Pisano, J.); Dr. Reddy's Laboratories, Ltd., et al. v. AstraZeneca AB, et al., No. 08-cv-02496 (D.N.J.) (Pisano, J.); AstraZeneca AB, et al. v. Ivax Corp. et al., No. 06-cv-1057 (D.N.J.) (Pisano, J.); AstraZeneca AB, et al. v. Ivax Corp. et al., No. 08-cv-4993 (D.N.J.) (Pisano, J.); IVAX Pharmaceuticals, Inc. v. AstraZeneca AB, et al., No. 08-cv-2165 (D.N.J.) (Pisano, J.); and any associated cases (collectively, the "Underlying Patent Litigations"), whether such information was disclosed through discovery, correspondence, court filings, court hearings, or otherwise, and which was designated as "Confidential," "Attorney Confidential," or "Highly Confidential", or bearing any other marking reasonably indicating an intent for confidential treatment, shall be treated as Protected Material under this Order.

[Plaintiffs make no allegations about any other patent actions involving Nexium, other than the ones listed above in defendants' proposal.]

b. Information that was designated as "Attorney Confidential," or "Highly Confidential" under the protective orders issued in the Underlying Patent Litigations shall be treated as if it was designated as Attorney Confidential under this Order, and information that was designated as "Confidential" shall be treated as if it was designated as Confidential under this Order. No party shall be required to apply new confidentiality legends to materials from the underlying patent litigations that already have such legends.



- 6. <u>Contested Designations.</u> A Receiving Party shall not be obligated to challenge the propriety of a Producing Party's designations of any Protected Material at the time such designation is made, and failure to do so shall not preclude a subsequent challenge thereto. If the receiving Party disagrees with the designation of any Protected Material, the Receiving Party may, after meeting and conferring with the Producing Party, move the Court for an order removing such Protected Material from the restrictions of this Protective Order.
- 7. Qualified Persons. A Receiving Party shall disclose Protected Material only to the following Qualified Persons, their clerical, support and secretarial staffs, paralegals, and assistants whose functions require access to Protected Material. All rights, obligations and restrictions in this Protective Order shall apply to such Qualified Persons as if they were the Receiving Party. Qualified Persons are limited to:
- a. Outside counsel of record in the above-captioned case, and other attorneys working at their respective law firms whose functions require access to Protected Material (collectively, "Outside Counsel"); provided that no Outside Counsel involved in prosecution of patents shall receive Attorney Confidential Protected Material without prior approval being obtained pursuant to Paragraph 8;
- b. The parties' in-house counsel in the above captioned cases; however, only

 Confidential Protected Material may be disclosed to the parties' in-house counsel; Attorney

 Confidential Protected Material may be disclosed to the parties' in-house counsel only with prior

 written approval pursuant to Paragraph 8; and provided that no in-house counsel of such parties
 to whom Protected Material is disclosed shall be directly involved with prosecution of patent
 applications or patent amendments for purposes of procuring a new or amended patent on

esomeprazole for a period of one (1) year following the conclusion of the above-captioned case, including all appeals.

- c. Outside experts or consultants retained by the Receiving Party or its counsel, such as independent technical experts, accountants, statisticians, economists, or other consultants, whose advice and consultation are being or will be used by such party or its counsel in connection with this action, including their stenographic or clerical personnel;
- d. Third-party contractors involved solely in providing litigation support services to Outside Counsel;
 - e. The Court and authorized staff;
- f. Court reporters, interpreters, translators, copy services, exhibit preparation services, and database and/or coding services retained on behalf of any party;
- g. Outside jury consultants, participants in jury studies (provided they sign nondisclosure agreements and are not permitted to take any confidential materials with them when they are done with the jury study), and trial consultants (including, but not limited to, graphics consultants); and
- h. Any other person that all parties and any producing third party have agreed to in advance in writing, according to Paragraph 8, below.
- 8. <u>Modification of List of Qualified Persons.</u> The list of persons to whom Protected Information may be disclosed, identified in Paragraph 7, may be expanded or modified by mutual agreement in writing by counsel for the Producing Party and the Receiving Party or Parties without the need to modify this Order.
 - 9. Notice and Acknowledgment of Order.

- a. Every Qualified Person to whom Protected Material or information contained therein is to be disclosed, summarized, described, characterized, or otherwise communicated or made available in whole or in part, first shall be advised that the material or information is being disclosed pursuant and subject to the terms of this Order.
- b. Before the first disclosure of Protected Material is made to a Qualified Person pursuant to Subparagraphs 7(b), 7(c), 7(g), and 7(h) Outside Counsel for the Receiving Party shall: (i) provide the Qualified Person with a copy of this Protective Order; (ii) explain its terms; and (iii) obtain the Qualified Person's signed Agreement To Abide By Protective Order, in the form of Exhibit A hereto.
- 10. Third Parties. Any third party from whom discovery is sought in the above-captioned case may, in accordance with this Order, designate some or all of its production as Protected Material, and each Receiving Party will have the same rights, obligations and restrictions as that Receiving Party has with respect to the Protected Material of any other Producing Party.
- Additional Parties. If an additional party joins or is joined in the above-captioned case, the newly joined party shall not have access to Protected Material until all parties to the above-captioned case agree to a supplemental Protective Order governing the protection of Protected Material.
- 12. Obligation of Outside Counsel. It shall be the responsibility of Outside Counsel to ensure strict compliance with the provisions of this Protective Order and to take reasonable and proper steps to ensure that all provisions thereof are made known to any person who shall examine Protected Material.

13. Depositions.

Plaintiffs' proposal	Defendants' proposal
a. Protected material may be disclosed to witnesses during depositions for purposes of discovery.	a. Protected Material may be disclosed to a witness at a deposition: (i) if the witness is an officer, director, or employee of a party who produced or received such Protected Material; or (ii) if the witness was formerly an officer, director, or employee of a party who produced or received such Protected Material, and the Protected Material existed during the period of his or her service or employment.

Continuing ... Provided, however, that disclosure of Protected Material during a deposition will not give rise to the bar on patent-related prosecution activities set forth in paragraph 7(b) above.

b. If a deposition concerns Protected Material, the Producing Party shall have the right to exclude from the portion of the deposition concerning such information any person not authorized in accordance with Paragraph 7 hereof to have access to such material.

14. Court Proceedings.

a. Nothing contained in this Order shall be construed to prejudice any party's right to use at trial or in any hearing before the Court any Protected Material. The parties reserve the right to seek additional relief from the Court with respect to Protected Material that may be presented at trial or in any hearing before the Court.

	Plaintiffs' proposal	Defendants' proposal
_	b. No prior disclosure is required, though counsel shall afford opposing counsel the usual degree of common courtesy in identifying materials to be used at trial in advance.	b. With respect to the use of Protected Material at trial or in any pretrial hearing before the Court, the party expecting to use such material shall give two (2) business days' advance notice (not less than 48 hours) to the Producing Party that identifies the material
		intended to be used, to enable the Producing Party to seek relief from the Court as appropriate, provided that the advance notice provisions shall not apply if (i) the Court indicates that the trial or pre-trial hearing will

be closed to persons other than those to whom disclosure of the material is permitted pursuant to Paragraph 7, (ii) circumstances arise in good faith that render such advance notice objectively unfeasible, and the party expecting to use such material informs the disclosing party as soon as possible and, in all events, prior to introducing or otherwise using the material, or (iii) the Protected Material was previously used in a public hearing. Notwithstanding the foregoing, a party may use another party's Protected Material on cross-examination or redirect examination at a hearing provided that party has given reasonable notice to the Producing Party that identifies the materials intended to be used, to enable the Producing Party to seek relief from the Court as appropriate. Citation of Protected Material in briefing or submissions to the Court, including in the body of expert reports (including charts, graphs, or other presentations of data), related to the subject matter of the hearing shall constitute notice for the purposes of this Subparagraph.

15. Designation of Protected Material in Deposition Transcripts.

a. Any person giving deposition testimony in this litigation as a representative of a party may designate any or all of the testimony as Confidential or Attorney Confidential. The person desiring to designate any portion of a deposition as Confidential or Attorney Confidential shall do so on the record while the deposition is being taken, either personally or through counsel. Additionally, any party may designate the transcript of any deposition (or any other testimony) as containing Confidential or Attorney Confidential Protected Material in accordance with this Order by notifying the opposing party in writing, within thirty (30) days of receipt of the transcript that it contains Protected Material and

specifying the specific pages and/or lines that should be designated as Confidential or Attorney Confidential.

- b. All transcripts shall be treated as Attorney Confidential and subject to this Protective Order until a time thirty (30) days after the transcript is received. After such thirty (30) day period has passed, any deposition testimony that has not been designated as Confidential or Attorney Confidential pursuant to Subparagraph 15(a) shall not be entitled to the protections afforded under this Protective Order.
- Designation by stamping or labeling consistent with Paragraph 4 need not be made with respect to materials provided for inspection by a Producing Party's counsel until copies of the materials are requested after inspection and selection by counsel. Making documents and things available for inspection shall not constitute a waiver of any claim of confidentiality, and all materials provided for inspection by the Producing Party's counsel shall, consistent with the instructions of the Producing Party, be treated as Attorney Confidential at the time of the inspection.
 - 17. Pleadings.
- a. The parties shall cooperate to avoid or minimize the need to file pleadings under seal.
- b. When filing electronically a motion, memorandum, deposition transcript, or other submission, with the Court, the filing party shall redact all Protected Material. An unredacted copy of the submission shall be served on all parties.
- c. Simultaneously with the electronic filing, the filing party shall make a Motion for Impoundment consistent with Local Rule 7.2. Only upon granting of the order, or

direction of the Court, shall the filing party submit Protected Material in conformance with Local Rule 7.2.

18. Non-waiver.

- a. The production of Produced Material under the terms of this Order in response to a request by an opposing party shall not be construed to mean that the Producing Party has waived any objection to the production, relevancy or admissibility of said Produced Material.
- b. Nothing contained herein shall preclude any party from opposing any discovery on any basis.
- admission or concession or permit an inference that the Protected Material has been properly designated as such. Any Receiving Party may at any time request that the Producing Party withdraw the Protected Material designation with respect to any document, object, or information. Such request shall be made to counsel for the Producing Party and shall identify the designated Protected Material that the Receiving Party contends has been inappropriately designated and the reasons supporting its contention. If the Producing Party does not agree to remove the Protected Material designation within five business days, then the party contesting the designation may request by motion that the Court redesignate the information as appropriate. The burden of demonstrating that the information is Protected Material shall be on the Producing Party. Notwithstanding the foregoing, should a dispute concerning the propriety of a designation arise during the course of a deposition, the requirement of five business days' prior written notice shall be inoperative, and Court intervention may be sought immediately.

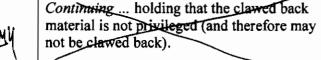
- d. Nothing in this Protective Order shall require disclosure of information that counsel contends is protected from disclosure by the attorney-client privilege the attorney work-product immunity, or any other applicable immunity or privilege (e.g., HIPAA) nor shall this Order, be construed to require disclosure in instances where such disclosure would breach an agreement with another to, or violate a court order to maintain such information in confidence. Any party that refuses to disclose any information based on the existence of an agreement with another or a court order to maintain its confidentiality shall identify the existence of the agreement or order in response to any request for the information. The parties agree to work in good faith to resolve any third-party confidentiality issues.
 - 19. Restrictions Not Imposed.
- a. This Protective Order shall not prevent any party from applying to the Court for relief therefrom, or from applying to the Court for further or additional protective orders.
- b. Nothing in this Order shall prevent any party from disclosing or using its own Protected Material for any purpose.
- c. Nothing in this Order shall bar or otherwise restrict any counsel who is a Qualified Person from rendering advice to a party-client in this action and in the course thereof, relying upon such attorney's examination of Protected Material; provided, however, that in rendering such advice and in otherwise communicating with such client, the attorney shall not directly or indirectly disclose any Protected Material to unauthorized persons.
- d. The restrictions and obligations set forth in this Protective Order relating to Protected Material shall not apply to any information that: (i) the parties agree, or the Court rules, is already public knowledge; (ii) the parties agree, or the Court rules, has become public

knowledge other than as a result of disclosure by the Receiving Party; (iii) is in the Receiving Party's legitimate possession independently of the Producing Party by means that do not constitute a violation of this Protective Order; or (iv) was, is, or becomes expressly released from being designated as Protected Material by the Producing Party or by order of the Court.

- 20. Inadvertent Production of Privileged Material.
- a. If information subject to a claim of attorney-client privilege or workproduct immunity is inadvertently or mistakenly produced, such production shall in no way
 prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or workproduct immunity for such information. If a party has inadvertently or mistakenly produced
 information subject to claim of immunity or privilege, upon request the information for which a
 claim of inadvertent production is made shall be returned or destroyed within ten (10) days of
 such request,

Plaintiffs' proposal	Defendants' proposal
Continuing with the sole exception that a	Continuing and that the information may not
copy may be kept for purposes of challenging	be used for any purpose. Moreover, any notes
the propriety of the claw back. Counsel shall	or summaries referring or relating to any such
make its best efforts to redact, or remove	inadvertently or mistakenly produced
references to the clawed back material in any	information subject to claim of immunity or
existing work product.	privilege shall be destroyed.

b. Within ten (10) days of the Producing Party's request for return or destruction of the inadvertently or mistakenly produced documents, the Producing Party shall provide a privilege log corresponding to the inadvertently or mistakenly produced documents. The party returning the inadvertently or mistakenly produced information may, as appropriate, move the Court for an Order



Continuing ... compelling production of such information relying on the information presented in the privilege log. The motion shall not disclose the substance of the inadvertently produced material, except to the extent than an *in camera* inspection of the



materials may be requested. The pendency of any such motion or dispute regarding the legitimacy of the claim of privilege or work product shall not entitle the moving party to
retain or use the information.

All of the protections of FRE 502, including but not limited to FRE 502(d), apply to inadvertently or mistakenly produced privileged or work product materials. If a party subsequently re-produces in redacted form a document that had previously been inadvertently produced and then was returned or destroyed in its entirety based on a request under this Paragraph, the subsequently-reproduced, redacted version of the document shall bear the same Bates number as the originally-produced document, along with an "-R" suffix.

- 21. Inadvertent Failure to Designate Protected Material. Inadvertent failure to designate any material which a Producing Party claims should be Protected Material will not be deemed a waiver of the right to make that designation. Upon receiving notice of such failure to designate, all Receiving Parties shall cooperate to restore the confidentiality of the inadvertently or unintentionally disclosed Produced Material. No party shall be held in breach of this Order if, prior to notification of such later designation, such Produced Material had been disclosed or used in a manner inconsistent with such later designation. The Producing Party shall provide substitute copies bearing the corrected designation. The Receiving Parties shall return or certify the destruction of the undesignated Produced Material.
- 22. <u>Unauthorized Disclosure.</u> In the event of disclosure of any Protected Material to a person not authorized to have access to such material, the party responsible for having made, and any party with knowledge of, such disclosure shall immediately

Plaintiffs' proposal	Defendants' proposal
[No proposal, Unnecessary,]	Continuing inform Outside Counsel for the
	party whose Protected Material has thus been



	disclosed of all known relevant information concerning the nature and circumstances of the disclosure. The responsible party shall also promptly
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take all reasonable measures to ensure that no further unauthorized disclosure or use of such information or materials is made. Each party shall cooperate in good faith in that effort.

23. Termination of Access.

- a. In the event that any person or party ceases to be engaged in the conduct of these actions, such person's or party's access to Protected Material shall be terminated, and all copies thereof shall be returned or destroyed in accordance with the terms of Subparagraph 24(b) hereof, except that such return or destruction shall take place as soon as practicable after such person or party ceases to be engaged in the conduct of these actions.
- b. The provisions of this Order shall remain in full force and effect as to any person or party who previously had access to Protected Material, except as may be specifically ordered by the Court or consented to by the Producing Party.

24. <u>Termination Of Action.</u>

- a. Subject to Subparagraph 24(b), this Protective Order shall survive the termination of this action. No part of the restrictions imposed by this Protective Order may be waived or terminated, except by the written stipulation executed by counsel of record for each designating party, or by an Order of the Court for good cause shown.
- b. Within sixty (60) days after entry of a final judgment or dismissal with prejudice (including appeals or petitions for review) or the execution of a settlement agreement, finally disposing of all issues raised in the above-captioned case, all Receiving Parties no longer in the case(s) shall: (i) return all Protected Material and any copies thereof to the appropriate

Outside Counsel who produced the Protected Material; or (ii) destroy such Protected Material. Each Receiving Party shall give written notice of such destruction to Outside Counsel for the Producing Party. However, Outside Counsel who are trial counsel may retain copies of all pleadings for archival purposes. Further, all notes, summaries, or other documents prepared by Qualified Persons under Subparagraphs 7(b)-(d) or 7(g)-(h), derived from or containing Protected Material, shall after the conclusion of the action, be kept within the files of Outside Counsel who are trial counsel for the Receiving Party creating such work product, or be destroyed. As to Protected Material reflected in computer databases or backup tapes, the Receiving Party shall delete all such Protected Material or shall impose passwords or designate the information in a manner reasonably calculated to prevent unauthorized access to the Protected Material. Any materials retained as permitted by this Paragraph shall be treated in accordance with the terms of this Protective Order so long as they continue to exist.

25. Notifications.

- a. All notices, disclosures, and requests required or permitted by this

 Protective Order shall be served by email by the close of the business day (5:00 p.m. ET), with
 confirmation by regular mail to the counsel of record if the sender of the email has any reason to
 believe that the email did not go through. The date by which a party receiving a notice shall
 respond, or otherwise take action, shall be computed from the close of the business day that the
 email was received.
 - b. Notifications shall be delivered to the following party representatives:

(1) For Plaintiffs

Thomas M. Sobol David S. Nalven Hagens Berman Sobol Shapiro LLP 55 Cambridge Parkway, Suite 301 Cambridge, MA 02142 Telephone: (617) 482-3700 Facsimile: (617) 482-3003 tom@hbsslaw.com davidn@hbsslaw.com

(2) For AstraZeneca

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(3) For Dr. Reddy's

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(5) For Teva

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- 26. <u>Jurisdiction.</u> The recipient of any Protected Material hereby agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any proceedings relating to the performance under, compliance with, or violation of this Protective Order.
- 27. <u>Modification</u>. Stipulations may be made, between Counsel for the respective parties, as to the application of this Order to specific situations, provided that such stipulations are recorded in writing or contained in the record of any oral proceeding. Nothing contained herein shall preclude any party seeking an order of the Court modifying or supplementing this Order.

SO ORDERED:

William G. Young

UNITED STATES DISTRICT JUDGE

Dated: Movember 24, 2012